IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

Sherry Cruz, individually and on behalf of all others similarly situated, Plaintiff, - against - Sanofi US Corporation, Defendant	1:21-cv-02351 Class Action Complaint Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations pertaining to plaintiff, which are based on personal knowledge:

1. Sanofi US Corporation ("defendant") manufactures, markets and sells over-the-counter ("OTC") external analgesic patches with an active ingredient of lidocaine (4%), under the Aspercreme brand ("Product").

I. Lidocaine in OTC Products

2. Lidocaine is a topical anesthetic used to treat pain by depressing sensory receptors in the nerve endings in the skin, which prevents pain signals from reaching the brain.

3. Lidocaine has been approved for use by the FDA since the early 1950s.

4. FDA regulates products containing lidocaine through "OTC Monographs."

5. The 1983 Tentative Final Monography for External Analgesic Drug Products for Over-the-Counter Human Use, ("TFM"), provides guidelines for labeling OTC products containing between 0.5% to 4% lidocaine.[1]

[1] 48 Fed. Reg. 5852-01 (Feb. 8, 1983).

6. Lidocaine is permitted for use as an active ingredient for only the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.[2]

7. Around 2003, the FDA initiated rulemaking to classify products which delivered lidocaine in a patch form. [3]

8. This was because there was no data on "[t]he safe and effective concentration" of lidocaine in this format, and uncertainties regarding the frequency of application that is considered safe and effective.

9. The FDA proposed categorizing external analgesic patches as Category III products, that require agency review and approval of the product and its labeling through a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA").[4]

II. Defendant's Misleading representations

10. Defendant's Product contains 4% lidocaine and is marketed as compliant with FDA regulations for Category I products, based on the numerous claims with respect to the Product's functions.

11. However, the Product does not comply with the TFM requirements for Category I ingredients and has not undergone review for products with Category III ingredients.

[2] 68 Fed. Reg. 42324-01, 42325-26 (July 17, 2003).
[3] *See* External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph, 68 Fed. Reg. 42324-01, 42326 (July 17, 2003).
[4] Category I products are considered "GRASE" and can be marketed without approvals required for Category III.

12. The Product's front label focuses on its ability to "numb" and affect "nerves."

- MAX STRENGTH
- NUMBS AWAY PAIN
- FAST ACTING
- TARGETS NERVES
- Flexible Fabric

- MAX STRENGTH LIDOCAINE
- NUMBS AWAY PAIN
- Desensitizes Aggravated Nerves
- FAST ACTING
- Targets More Pain Receptors*
- Non Irritating

13. The lidocaine percentage is indicated in the fine print, next to "LIDOCAINE" or in the lower right corner of the label.

14. The side panels indicate "Targeted Relief" for the main joint areas.

- Targeted No Mess Relief
- Easy to Apply & Remove
- Flexible Fabric

- TARGETED RELIEF
- BACK, NECK & SHOULDER
- KNEE & ELBOW
- HAND & WRIST
- FOOT, ANKLE & LEG

A. Max Strength and Fast Acting Claims

15. The "Max Strength" claims are misleading because it implies the Product contains and delivers the maximum amount of lidocaine in patch form to the affected area.

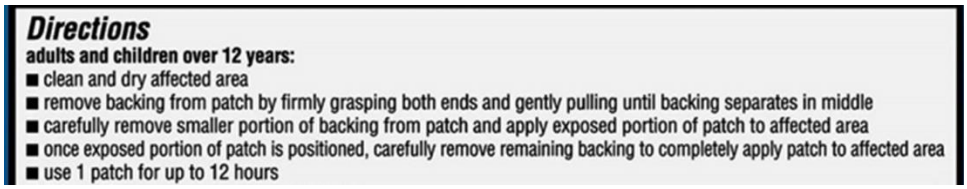
16. However, this is false because other patch products deliver more lidocaine to affected areas, are more effective, are approved by the FDA for more purposes than defendant's Product and are supported by clinical studies.

17. The "fast acting" claim is misleading because it implies the Product provides immediate pain relief when it does not.

18. The Product uses a thicker patch than similar products, resulting in a less effective and slower delivery of lidocaine to the affected area.

B. "12 hours" Claim

19. The Directions on the Drug Facts state to "use 1 patch for up to 12 hours."


Directions
adults and children over 12 years:
- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

20. The other representations, such as "FLEXIBLE FABRIC," "Easy to Apply & Remove," and "Non Irritating," further the impression that the Product will adhere to the body and continuously relieve pain for the promised amount of time – 12 hours.

21. However, numerous studies and reports revealed that users of the Product seldom experience anything close to 12 hours of relief, because the patch fails to adhere for even six hours.

22. According to the FDA, when a patch delivering lidocaine becomes "partially detached," its efficacy of delivery and absorption of the active ingredient is greatly reduced.

C. "Numb" or "Completely Block Pain" Claims

23. The claim that the Product "NUMBS AWAY PAIN" falsely imply the Product completely blocks pain receptors, eliminates responses to painful stimuli and provides a numbing sensation.

24. These statements are misleading to consumers because whether a lidocaine patch like the Product is capable of these effects depends on the how it is used.[5]

[5] FDA concluded that "[c]laims regarding numbness or similar claims, such as completely blocking pain receptors or abolishing responses to painful stimuli, may be misleading to consumers because the manner in which external analgesic drug products are used determines whether they cause numbness or not." Id.

25. Additionally, the FDA determined that statements such as "numb[] away pain" on external analgesic products like the Product are misleading to consumers because it is not capable to perform this function.

D. "Nerves" and "Pain Receptor" Claims are Misleading

26. The label and marketing claim the Product "TARGETS NERVES," "DESENSITIZES AGGRAVATED NERVES," "Targets More Pain Receptors,*" and that the Product will "Relieve the nerves. Stop the pain."

27. These representations imply that the Product provides pain relief by desensitizing nerves and/or pain receptors.

28. The asterisked claim is qualified but in such small print it cannot overcome the message consumers take away from this claim.

29. Consumers understand these representations to mean the Product contains ingredients that target nerves and pain receptors when this is not true.

30. Since consumers associate "nerves" and "pain receptors" with medical treatments typically requiring a prescription (and FDA approval), seeing these claims tells them the Product can achieve these results.

31. However, the Product cannot achieve these results, which is why the FDA prohibits external analgesic products containing lidocaine from making these types of claims.[6]

E. Misleading as to Product's Indications

32. The side panels indicate the Product provides "Targeted Relief" for the main joint areas: (1) BACK, NECK & SHOULDER, (2) KNEE & ELBOW, (3) HAND & WRIST and (4) FOOT, ANKLE & LEG.

33. These representations give consumers the impression the Product can treat neuropathic and musculoskeletal pain, including back and spinal pain.

34. However, the Product is only authorized for "temporary relief" of "pain," "itching," or "pain and itching" "associated with" "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritations."[7]

[6] 48 Fed. Reg. 5852-01, 5860-61 (Feb. 8, 1983).
[7] 48 Fed. Reg. 5852-01, 5868 (Feb. 8, 1983).

35. The only place where the accurate indications are disclosed is buried within the fine print and miniscule font of the Drug Facts: "***Uses*** temporarily relieves minor pain."

Drug Facts

Active ingredient	**Purpose**
Lidocaine 4%	Topical anesthetic

Uses temporarily relieves minor pain

Warnings

For external use only

Do not use ■ more than 1 patch on your body at a time or on cut, irritated or swollen skin ■ on puncture wounds ■ for more than one week without consulting a doctor

When using this product ■ use only as directed. Read and follow all directions and warnings on this carton. ■ do not allow contact with the eyes ■ do not bandage tightly or apply local heat (such as heating pads) to the area of use ■ do not use at the same time as other topical analgesics ■ dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if ■ condition worsens ■ redness is present ■ irritation develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:
■ clean and dry affected area ■ remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle ■ carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area ■ once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area ■ use 1 patch for up to 12 hours
children 12 years or younger: ask a doctor

Inactive ingredients aluminum glycinate, aluminum hydroxide, cellulose gum, glycerin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, silica, sodium polyacrylate, tartaric acid, titanium dioxide, urea, water

III. Conclusion

36. Reasonable consumers must and do rely on defendant to honestly describe the components and features of the Product, relative to itself and other comparable products.

37. Plaintiff did not scrutinize the drug facts nor was she required to do so.

38. No independent, credible studies support the claims made in support of the Product.

39. Even if Plaintiff scrutinized the drug facts, it would not cure the misrepresentations.

40. Reasonable consumers must and do rely on defendant to honestly describe the components and features of the Product.

41. Defendant misrepresented the Product through affirmative statements, half-truths, and omissions.

42. Defendant sold more of the Product and at a higher prices than it would have in absence of this misconduct, resulting in additional profits at the expense of consumers.

43. Had Plaintiff and proposed class members known the truth, they would not have bought the Product or would have paid less for it.

44. Plaintiff paid more for the Product based on the representations than she would have otherwise paid.

45. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than $8.52 for five patches, excluding tax, compared to other similar products represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

Jurisdiction and Venue

46. Jurisdiction is proper pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

47. Plaintiff Sherry Cruz is a citizen of Illinois.

48. Defendant Sanofi US Corporation is a Delaware agricultural cooperative corporation with a principal place of business in Bridgewater, Somerset County, New Jersey.

49. Diversity exists because plaintiff Sherry Cruz and defendant are citizens of different states.

50. Upon information and belief, sales of the Product and any available statutory and other monetary damages, exceed $5 million during the applicable statutes of limitations, exclusive of interest and costs.

51. Venue is proper because a substantial part of the events or omissions giving rise to the claim occurred here – the purchase of plaintiff and her experiences identified here.

Parties

52. Plaintiff Sherry Cruz is a citizen of Chicago, Cook County, Illinois.

53. Defendant Sanofi US Corporation is a Delaware corporation with a principal place of business in Bridgewater, New Jersey, Somerset County.

54. Defendant is a French multinational pharmaceutical company which produces prescription medications, medical devices and OTC products.

55. Plaintiff purchased one of the Lidocaine Products on at least one occasions within the statutes of limitations for each cause of action, between February and March 2021, at stores including CVS, 741 W 31st St, Chicago, IL 60616.

56. Plaintiff bought the Product because she expected it would provide the type of pain relief it represented.

57. The Product was worth less than what Plaintiff and consumers paid and she would not have paid as much absent Defendant's false and misleading statements and omissions.

58. Plaintiff paid more for the Product than she would have paid otherwise.

59. Plaintiff intends to, seeks to, and will purchase the Product again when she can do so with the assurance that Product's representations about its components and ingredients are consistent with its representations.

Class Allegations

60. The class will consist of all purchasers of the Product who reside in Illinois during the applicable statutes of limitations.

61. Plaintiff seeks class-wide injunctive relief based on Rule 23(b) in addition to a monetary relief class.

62. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiff and class members are entitled to damages.

63. Plaintiff's claims and basis for relief are typical to other members because all were

subjected to the same unfair and deceptive representations and actions.

64. Plaintiff is an adequate representative because her interests do not conflict with other members.

65. No individual inquiry is necessary since the focus is only on defendant's practices and the class is definable and ascertainable.

66. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

67. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

68. Plaintiff seeks class-wide injunctive relief because the practices continue.

Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1, et seq.

(Consumer Protection Statute)

69. Plaintiff incorporates by reference all preceding paragraphs.

70. Plaintiff and class members desired to purchase a product which would provide the type of pain relief it represented.

71. Defendant's false and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

72. Defendant misrepresented the Product through statements, omissions, ambiguities, half-truths and/or actions.

73. Plaintiff relied on the representations.

74. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability and
Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq*.

75. The Product was manufactured, labeled and sold by defendant and expressly and impliedly warranted to plaintiff and class members that it possessed attributes and capabilities which it did not.

76. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

77. This duty is based on Defendant's outsized role in the market for this type of Product – a global international pharmaceutical company with hundreds of brands.

78. Plaintiff provided or will provide notice to defendant, its agents, representatives, retailers and their employees.

79. Defendant received notice and should have been aware of these issues due to complaints by regulators, competitors, and consumers, to its main offices over the past several years.

80. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable because they were not fit to pass in the trade as advertised.

81. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

82. Defendant had a duty to truthfully represent the Product, which it breached.

83. This duty is based on defendant's position, holding itself out as having special knowledge and experience in the sale of OTC pain relief products.

84. The representations took advantage of consumers' cognitive shortcuts made at the

point-of-sale and their trust in defendant.

85. Plaintiff reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, their purchases of the Product.

86. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

87. Defendant misrepresented and/or omitted the attributes and qualities of the Product.

88. Defendant's fraudulent intent is evinced by its knowledge of the relevant regulations, as many of its misleading claims are carefully worded to avoid the obvious prohibited statements but still misleading.

Unjust Enrichment

89. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying plaintiff as representative and the undersigned as counsel for the class;
2. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;

3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages, statutory damages pursuant to any statutory claims and interest pursuant to the common law and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiff's attorneys and experts; and
6. Other and further relief as the Court deems just and proper.

Dated: May 1, 2021

Respectfully submitted,

Sheehan & Associates, P.C.
/s/Spencer Sheehan
Spencer Sheehan
60 Cuttermill Rd Ste 409
Great Neck NY 11021-3104
Tel: (516) 268-7080
Fax: (516) 234-7800
spencer@spencersheehan.com